prophylactic agent from the matrix, wherein the drug is released over shorter periods of time as compared to release from matrices not incorporating the hydrophobic or amphiphilic compound,

the matrix being formed by a method comprising emulsifying a polymer solution, the therapeutic or prophylactic agent, a hydrophobic or amphiphilic compound, and a pore forming agent, wherein the pore forming agent is added as a solution of pore forming agent or is added as a volatile salt, then removing the solvent and the pore forming agent to produce a matrix.

Remarks

Amendments

Claim 20 has been amended to more clearly distinguish the prior art, as discussed below. Claim 20 now recites that the pore forming agent is added either as a solution or as a volatile salt. Support for the amendment is found in the application at page 15, line 27 to page 16, line 10.

Rejection under 35 U.S.C. section 102

Claims 20-24, and 27-32 were rejected under 102(e) as disclosed by U.S. Patent No. 5,942,253 to Gombotz, et al. This rejection is respectfully traversed if applied to the amended claims.

Anticipation requires the disclosure, in a single prior art reference, of every element of the claim. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986). Absence of a claimed element from a prior art reference negates anticipation. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 224 U.S.P.Q. 409 (Fed. Cir. 1984).

Gombotz discloses pore forming agents at col. 9, lines 51-55, as the examiner has correctly noted. They are added as particulates (col. 9, line 54). There is no mention of volatile salts, only inorganic salts and sugars. Anticipation is not achieved absent a disclosure of **each**

U.S.S.N.: 09/731,412
Filed: December 6, 2000
AMENDMENT

claimed feature. Gombotz fails to disclose each claimed feature (addition of pore forming agent as a solution; addition of volatile salt pore forming agents). Therefore Gombotz fails to anticipate the claims as amended.

Allowance of claims 21-34 is therefore earnestly solicited.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the enclosed Amendment and all documents shown as being attached is being facsimile transmitted to the U. S. Patent and Trademark Office on the date shown below.

Date: June 6, 2002

Jean Hicks

U.S.S.N.: 09/731,412
Filed: December 6, 2000
AMENDMENT

APPENDIX: Marked up Claims as Amended

20. (three times amended) A method for administering a therapeutic or prophylactic agent comprising administering to a patient a matrix for delivery of a therapeutic or prophylactic agent,

wherein the matrix is formed of a biocompatible polymer having incorporated therein an therapeutic or prophylactic agent and an effective amount of a hydrophobic or amphiphilic compound to modify the diffusion of water into the matrix and the release of the therapeutic or prophylactic agent from the matrix, wherein the drug is released over shorter periods of time as compared to release from matrices not incorporating the hydrophobic or amphiphilic compound,

the matrix being formed by a method comprising emulsifying a polymer solution, the therapeutic or prophylactic agent, a hydrophobic or amphiphilic compound, and a pore forming agent, wherein the pore forming agent is added as a solution of pore forming agent or is added as a volatile salt, then removing the solvent and the pore forming agent to produce a matrix.

21. The method of claim 20 wherein the matrix is in the form of microparticles.

22. The method of claim 20 wherein the hydrophobic or amphiphilic compound is incorporated into the matrix at a ratio of between 0.01 and 60 by weight of hydrophobic compound to weight of polymer.

23. The method of claim 20 wherein the hydrophobic or amphiphilic compound is a lipid incorporated into the matrix at a ratio of between 0.01 and 30 (weight lipid/weight matrix material).

24. The method of claim 23 wherein the lipid is selected from the group consisting of fatty acids and derivatives, mono-, di and triglycerides, phospholipids, sphingolipids, cholesterol and steroid derivatives, oils, vitamins and terpenes.

25. The method of claim 24 wherein the lipid is a phospholipid selected from the group consisting of phosphatidic acids, phosphatidyl cholines with both saturated and unsaturated lipids, phosphatidyl ethanolamines, phosphatidylglycerols, phosphatidylserines, phosphatidylinositols, lysophosphatidyl derivatives, cardiolipin, and β-acyl-γ-alkyl phospholipids.

26. The method of claim 25 wherein the phospholipid is selected from the group consisting of dioleoylphosphatidylcholine, dimyristoylphosphatidylcholine, dipentadecanoylphosphatidylcholine dilauroylphosphatidylcholine, dipalmitoylphosphatidylcholine, distearoylphosphatidylcholine, diarachidoylphosphatidylcholine, dibehenoylphosphatidylcholine, ditricosanoylphosphatidylcholine, dilignoceroylphatidylcholine; and phosphatidylethanolamines.

27. The method of claim 20 wherein the agent is a therapeutic agent.

28. The method of claim 20 wherein the matrix is formed of a bioadhesive polymer.

29. The method of claim 20 wherein the matrix is formed of a polymer selected from the group consisting of poly(hydroxy acids), polyanhydrides, polyorthoesters, polyamides, polycarbonates, polyalkylenes, polyalkylene glycols, polyalkylene oxides, polyalkylene terepthalates, polyvinyl alcohols, polyvinyl ethers, polyvinyl esters, polyvinyl halides, polyvinylpyrrolidone, polysiloxanes, poly(vinyl alcohols), poly(vinyl acetate), polystyrene, polyurethanes and co-polymers thereof, synthetic celluloses, polyacrylic acids, poly(butyric acid), poly(valeric acid), and poly(lactide-co-caprolactone), ethylene vinyl acetate, copolymers and blends thereof.

30. The method of claim 20 wherein the matrix is formed of a protein or polysaccharide.

31. The method of claim 20 wherein the matrix is in a pharmaceutically acceptable carrier for topical application or application to a mucosal surface.

32. The method of claim 20 wherein the matrix is in a pharmaceutically acceptable carrier for injection.

33. The method of claim 20 wherein the matrix is formulated for administration rectally or vaginally.

34. The method of claim 21 wherein the microparticles are formulated for pulmonary administration.